



Early Access to Medicines Scheme – Treatment protocol – Information for patients

Introduction

The aim of the Early Access to Medicines Scheme (EAMS) is to provide earlier availability of promising new unlicensed medicines (medicines that do not have a marketing authorisation or are used outside their licence) to UK patients that have a high unmet clinical need. The medicines included in the scheme are those that are intended to treat, diagnose or prevent seriously debilitating or life-threatening conditions where there are no adequate treatment options. More information about the scheme can be found here:

<http://www.mhra.gov.uk/Howweregulate/Innovation/EarlyaccesstomedicinesschemeEAMS/index.htm>

The information below is intended for you, the patient, and is provided by the pharmaceutical company (called scientific opinion holder) that manufactures the EAMS medicine. This medicine, which does not yet have a drug licence or is used outside its licence, may also be used in combination with other medicines. More information about medicines licensing can be found here:

<http://www.nhs.uk/conditions/medicines-information>

This medicine can be prescribed for individual patients to meet specific needs provided they are given sufficient information about the medicine to make an informed decision. The prescribing doctor will be responsible for giving you all the information you need to make this decision and for obtaining informed consent from you prior to treatment. You will be asked to sign a form to confirm that you are providing informed consent to receiving the EAMS treatment. Information on consent can be found here:

<https://www.nhs.uk/conditions/Consent-to-treatment>

The information below is provided to help you decide with the prescribing doctor on whether to use the EAMS medicine and helps explain how to use it in accordance with the pharmaceutical company's instructions for safe and proper use. The information below may change during the time you are using the medicine if more data become available. The prescribing doctor will highlight to you any changes that you need to be aware of.

Whilst you are using this medicine, data will be collected on the use and safety profile of the medicine, to ensure that the benefits of taking the medicine continue to outweigh any potential risks. The prescribing doctor will answer all your questions during and after the treatment and will provide you with contact details that you should use in case of any events or problems.

Each patient enrolled in the scheme will continue to receive the EAMS product until the end of the treatment in line with prescribing and NHS guidance and as long as benefit is seen. In rare cases where the EAMS treatment may not be available anymore, your prescribing doctor will discuss other options with you.

Information for the patient

Abrocitinib 100 mg film-coated tablets

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

In addition to this leaflet, your doctor will also give you a Patient Card, which contains important safety information that you need to be aware of before you are given abrocitinib and during treatment with abrocitinib. Keep this Patient Card with you.

What is in this leaflet

1. What abrocitinib is and what it is used for
2. What you need to know before you take abrocitinib
3. How to take abrocitinib
4. Possible side effects
5. How to store abrocitinib
6. Contents of the pack and other information

1. What abrocitinib is and what it is used for

What abrocitinib is

Abrocitinib is a medicine that contains the active substance abrocitinib.

Abrocitinib is a Janus kinase inhibitor, which reduces inflammation and itch in atopic dermatitis.

What abrocitinib is used for

Abrocitinib is used to treat adults and adolescents 12 years of age and older with severe atopic dermatitis, also known as atopic eczema.

Abrocitinib may be used with eczema medicines that you apply to the skin or it may be used on its own.

How abrocitinib works

Using abrocitinib for atopic dermatitis (atopic eczema) can improve the condition of your skin and reduce itching. Abrocitinib has also been shown to improve symptoms of pain, anxiety, and depression associated with atopic dermatitis. In addition, abrocitinib helps improve your sleep disturbance and overall quality of life.

2. What you need to know before you take abrocitinib

Do not take abrocitinib

- if you are allergic to abrocitinib or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant

Warnings and precautions

Before starting abrocitinib, tell your healthcare provider if:

- you have an infection or have the following symptoms: fever, sweating, or chills, muscle aches, cough or shortness of breath, blood in your phlegm, weight loss, diarrhoea or stomach pain, burning when you urinate or urinating more often than usual, feeling very tired – abrocitinib can reduce your body's ability to fight infections and so may worsen an infection that you already have, or make it more likely for you to get a new infection
- you have had tuberculosis or have been in close contact with someone with tuberculosis. Your doctor will test you for tuberculosis before starting abrocitinib and may retest during treatment
- you have had shingles (also known as herpes zoster), because abrocitinib may allow it to come back. Tell your doctor if you get a painful skin rash with blisters as these can be signs of shingles
- you have had a rapidly spreading painful rash, blisters or sores (with or without fever) known as eczema herpeticum or Kaposi's varicelliform eruption
- you have ever had hepatitis B or hepatitis C
- your liver does not work as well as it should
- you have recently had or plan to have a vaccination (immunisation) – this is because live vaccines are not recommended while using abrocitinib
- you have had blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism). Tell your doctor if you get a painful swollen leg, chest pain or shortness of breath as these can be signs of blood clots in the veins
- you have cancer or have had any cancer – because your doctor will have to decide if you can still be given abrocitinib

Additional monitoring tests

Your healthcare provider should do blood tests before you start taking abrocitinib and also while you are taking abrocitinib, to check for the following:

- low lymphocyte counts. Lymphocytes are white blood cells that help the body fight off infections
- low platelet counts. Platelets are small, cell fragments in our blood that form clots and stop or prevent bleeding
- high blood fat (cholesterol) to ensure that treatment with abrocitinib is not causing problems

You should not take abrocitinib if your lymphocyte count or platelet count is too low. Your healthcare provider may stop or interrupt your abrocitinib treatment for a period of time if there are changes in these blood test results. You may also have changes in other laboratory tests, such as your blood cholesterol levels.

Children

The safety and benefits of abrocitinib are not yet known in children with atopic dermatitis below the age of 12 years.

Other medicines and abrocitinib

Tell your doctor if you are taking, have recently taken or might take any other medicines, including prescription and over-the-counter medicines. Taking abrocitinib with certain other medicines could cause side effects. Your doctor might change the dose or tell you to stop taking abrocitinib if you are taking some of these other medicines.

Pregnancy and breast-feeding

Pregnancy

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You should use an effective method of contraception to avoid becoming pregnant during treatment with abrocitinib, and for at least 1 month after the last dose of abrocitinib treatment. You must tell your doctor if you become pregnant as abrocitinib should not be used during pregnancy.

Breast-feeding

You should not use abrocitinib whilst breast-feeding, as abrocitinib may pass into your breast milk. You and your doctor should decide whether you will breast-feed or use abrocitinib. You should not do both.

Driving and using machines

Abrocitinib has no or limited effect on your ability to drive or use machines.

Abrocitinib contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say abrocitinib is essentially 'sodium-free'.

Abrocitinib contains lactose

Abrocitinib 100 mg film-coated tablet contains 2.73 mg of lactose, corresponding to the amount of lactose monohydrate in the film coating material Opadry® II White 33G28523.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take abrocitinib

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

The recommended dose in adults and adolescents (12 years of age and older) is 100 mg or 200 mg (one tablet for 100 mg, or two tablets for 200 mg) at the same time once daily, based on your doctor's assessment of the treatment needs and clinical condition.

Your doctor will decide which dose of abrocitinib is right for you.

Your doctor may reduce the dose if you have kidney problems or if you are prescribed certain other medicines. Your doctor may also stop treatment temporarily or permanently if blood tests show low lymphocyte or platelet counts.

Abrocitinib is for oral use. You should swallow your tablet whole with water. Do not split, crush, chew or break the tablet before swallowing.

You can take the tablets either with or without food. If you experience nausea (feeling sick in the stomach), taking your tablet with food may improve nausea. To help you remember to take abrocitinib, you may find it easier to take it at the same time every day.

If you take more abrocitinib than you should

If you take more abrocitinib than you should, contact your doctor. You may get some of the side effects described in section 4.

If you forget to take abrocitinib

- If you miss a dose, take it as soon as you remember.
- If you forget your dose for an entire day, just skip the missed dose and take only a single dose as usual the following day.
- Do not take a double dose to make up for a forgotten tablet.

If you stop taking abrocitinib

You should not stop taking abrocitinib without discussing this with your doctor. If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some may be serious and need medical attention.

Serious side effects

These types of side effects are uncommon (may affect up to 1 in 100 people).

Talk to your doctor or get medical help straight away if you get any signs of:

- infections such as
 - painful skin rash with blisters (shingles), or
 - a rapidly spreading painful rash, blisters or sores (with or without fever) known as eczema herpeticum or Kaposi's varicelliform eruption, or
 - warm, red, or painful skin or sores on your body
- blood clots in the lungs, legs or pelvis such as swelling, pain or tenderness in one or both legs, a sudden or unexplained chest or upper back pain, shortness of breath or difficulty breathing

Very common (may affect more than 1 in 10 people)

Feeling sick in the stomach (nausea)

Common (may affect up to 1 in 10 people)

- Cold sores (herpes simplex)
- Vomiting
- Upper abdominal pain
- Headache
- Dizziness
- Acne
- Increase in an enzyme called creatine phosphokinase, shown by blood test

Uncommon (may affect up to 1 in 100 people)

- Low platelet count (cell fragments involved in clotting), shown by blood test
- Low lymphocyte count (a type of white blood cell), shown by blood test
- High levels of blood cholesterol (a type of fat in the blood), shown by blood test

Reporting of side effects

Tell your doctor immediately if you get any side effects. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store abrocitinib

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the use by date which is stated on the container.

Store at 15 °C – 30 °C.

Store in the original package in order to protect from moisture.

Do not use this medicine if you notice the tablets show visible signs of deterioration (for example, are broken or discoloured).

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What abrocitinib contains

Abrocitinib 100 mg film-coated tablet

- The active substance is abrocitinib.
Each tablet contains 100 mg of abrocitinib.

The other ingredients are:

- Tablet core: microcrystalline cellulose, dibasic calcium phosphate anhydrous, sodium starch glycolate, magnesium stearate.

Film-coat: hypromellose (E464), titanium dioxide (E171), lactose monohydrate, macrogol, triacetin (E1518).

What abrocitinib looks like and contents of the pack

Abrocitinib 100 mg film-coated tablet is white and round in appearance.

The tablets are provided in a high-density polyethylene (HDPE) bottle with closure. Each pack contains 98 film-coated tablets.

Scientific Opinion Holder

Pfizer Limited
Ramsgate Road
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Manufacturer

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This protocol was last revised in Jan 2021

Additional information

You will also be provided with the following items:

- Informed Consent/Assent Form
- Patient Card, a wallet size card to be completed and given to each patient and carried with them

Informed Consent/Assent Form

All patients will have the EAMS explained to them using the Informed Consent/Assent form. You will be asked to sign this form and a copy will be given to you to keep.

Patient Card

You will be given a Patient Card before starting treatment with abrocitinib. You must keep this patient card with you at all times during the treatment and for at least 1 month after completing your treatment. The card summarises that you are currently receiving abrocitinib, the important side effects for which you need to seek assistance should they occur, details of your treating doctor, out of hours contact details and the company contact details.

Patient data to be collected

Patient data collected during the scheme are mostly used for safety surveillance and cannot replace a proper clinical trial to support a marketing authorisation. These data are required by the Medicines and Healthcare products Regulatory Agency (MHRA) to help verify that the patient's condition complies with the EAMS indication and help interpret the side effects and other events occurring during and after the

EAMS treatment. These data include patient's initials, year of birth, gender, diagnosis, previous treatments, comorbidities, and concomitant medications.

Contact information

Contact Details for Medical Information

Pfizer Limited Medical Information, Tel +44 (0) 1304 616161